

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: July 30, 2013

SUBJECT: Picloram: Tier I Review of Human Incidents

PC Code: 005101, 005102, 005104
Decision No.: 480872
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcode: D413236
Registration No.: NA
Regulatory Action: NA
Case No.: NA
CAS No.: 1918-02-1, 6753-47-5, 2545-60-0
40 CFR: NA

Ver Apr.08

FROM: Elizabeth Evans, Environmental Protection Specialist
Toxicology and Epidemiology Branch
Health Effects Division (7509P)
and
Shanna Recore, Industrial Hygienist
Toxicology and Epidemiology Branch
Health Effect Division (7509P)

A handwritten signature in black ink, appearing to read "Elizabeth Evans", enclosed within a large, hand-drawn oval.

A handwritten signature in black ink, appearing to read "Shanna Recore".

THROUGH: David Miller, Acting Branch Chief
Toxicology and Epidemiology Branch
Health Effects Division (7509P)

A handwritten signature in black ink, appearing to read "David Miller", with the date "30 Jul 2013" written next to it.

TO: Margarita Collantes, Risk Assessor
Risk Assessment Branch II
Health Effects Division (7509P)
and
Eric Miederhoff, Chemical Review Manager
Risk Management & Implementation Branch 3
Pesticide Re-evaluation Division (7508P)

Summary and Conclusions

Based on the low frequency and severity of incident cases reported for, there does not appear to be a concern at this time that would warrant further investigation. The Agency will continue to monitor the incident information and if a concern is triggered, additional analysis will be included in the risk assessment.

Detailed Review

I. ACTION REQUESTED

This review is intended to fulfill our requirement to docket summaries of incident data that were reported to the Agency, as well as to ensure human incident data and the Agricultural Health Study (AHS) are part of the problem formulation phase of registration review. Reports of adverse health effects allegedly due to a specific pesticide exposure (*i.e.*, an “incident”) are largely self-reported and therefore, generally speaking, neither exposure to a pesticide or reported symptom (or the connection between the two) is validated or otherwise confirmed. Typically, causation cannot be determined based on incident data. However, incident information can be an important source of feedback to the Agency: incidents of severe outcome, or a suggested pattern or trend among less severe incidents, can signal the Agency to further investigate a particular chemical or product. Observational epidemiology studies relate the risk of disease, *e.g.*, cancer, and exposure to an agent such as a pesticide product in the general population or specific sub-groups like pesticide applicators.

II. BACKGROUND

Picloram is a systemic herbicide used to control deeply rooted herbaceous weeds and woody plants in rights-of-way, forestry, rangelands, pastures, and small grain crops. It is applied in the greatest amounts to pasture and rangeland, followed by forestry. Picloram products have no household or residential uses.¹

For this evaluation, both the OPP Incident Data System (IDS) and the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR) databases were consulted for pesticide incident data on the active ingredient picloram (pc codes: 005101, 005102, 005104). The purpose of the database search is to identify potential patterns in the frequency and severity of the health effects attributed to picloram exposure. Picloram is included in the AHS, but is currently in data collection (Phase III); therefore the data are not available for this review.

III. RESULTS/DISCUSSION

a. IDS (Incident Data System)

OPP’s IDS includes reports of alleged human health incidents from various sources, including mandatory Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6(a)(2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in IDS. IDS contains reports from across the U.S. and most incidents have all relevant product information recorded. Reports

¹ Excerpt from the Picloram Fact Sheet, found online at:
<http://www.epa.gov/oppsrrd1/REDs/factsheets/0096fact.pdf>

submitted to the IDS represent anecdotal reports or allegations only, unless otherwise stated in the report.

IDS records incidents in one of two modules: Main IDS and Aggregate IDS:

- Main IDS contains incidents resulting in higher severity outcomes and provides more detail with regard to case specific. This system stores incident data for death, major and moderate incidents, and it includes information about the location, date and nature of the incident. Main IDS incidents involving only one pesticide are considered to provide more certain information about the potential effects of exposure from the pesticide.
- Aggregate IDS contains incidents resulting in less severe human incidents (minor, unknown, or no effects outcomes). These are reported by registrants only as counts in what are aggregate summaries.

For the Main IDS, from January 1, 2008 to June 11, 2013, there was 1 incident reported as a single chemical only incident in the database. This incident was classified as moderate severity. There were 28 additional incidents reported involving more than one chemical.² It should be noted there was one incident reported as a lawsuit to IDS that was not considered in this report. Overall, there are few incidents involving picloram reported to IDS.

In Aggregate IDS, from January 1, 2008 to February 19, 2013, there were 88 reported incidents involving picloram.

b. SENSOR-Pesticides

The SENSOR-Pesticides database covers 11 states from 1998-2009, although reporting varies from state to state. Cases of pesticide-related illnesses are ascertained from a variety of sources, including: reports from local Poison Control Centers, state Department of Labor workers' compensation claims when reported by physicians, reports from State Departments of Agriculture, and physician reports to state Departments of Health. Although both occupational and non-occupational incidents are included in the database, SENSOR-Pesticides focuses on occupational pesticide incidents, and is of particular value in providing that information. The state coordinator at each of the 11 respective state Departments of Health conducts case follow-up activities such as obtaining medical records to verify symptoms and severity. Using standardized protocol and case definitions derived from poison center reporting, the state SENSOR-Pesticide coordinator enters the incident information into the state-based system which is sent to NIOSH annually to be aggregated.

A query of SENSOR-Pesticides 1998-2009 identifies a total of 36 cases stemming from 27 events. Of these cases, 4 cases involved a single active ingredient (ai). Of the single ai cases,

² There were also four incidents that occurred in Brazil, 1 in Australia and 2 in Canada. Foreign incidents are not reviewed in detail because of the potential differences in the exposure patterns, use practices, and product formulation.

two were work-related and two were not work-related. One was high in severity and three were low in severity. Symptoms reported for the single ai cases are summarized in Table 2.

The high severity case occurred in Texas in 2004; the case description states, “According to medical records, case was spraying weeds at work, barrel of chemical bounced off the forklift and he ran over it. The lid burst open and chemical splashed all over him. The case took his clothes off, washed down with water, and irrigated his eyes.” The case experienced a chemical burn to the eye and corneal abrasion.

Table 2. SENSOR-Pesticides 1998-2009: Reported Health Effects for Picloram Cases (N=4)	
Health Effect	# of Times Reported
Dermal	1
Ocular	3
Respiratory	1
Gastrointestinal	1
Renal	0
Nervous System	1
Cardiovascular	0
Miscellaneous	0
* Cases may report multiple health effects	

c. Agricultural Health Study (AHS)

The AHS is a high quality, prospective epidemiology study evaluating the link between pesticide use and various health outcomes including cancer. The AHS includes private and commercial pesticide applicators and their spouses. If there are AHS findings relevant to a particular pesticide going through registration review, the Agency will ensure they are considered in the problem formulation/scoping phase of the process and, if appropriate, fully reviewed in the risk assessment phase of the process. The AHS includes information on use of 50 different pesticide active ingredients commonly used in agriculture.

Picloram is included in the AHS; however, it is only in phase III (data collection) and these data are not yet available for review. Therefore AHS does not provide information for this report.

IV. CONCLUSION

Based on the low frequency of incident cases reported for picloram inn both IDS and SENSOR-Pesticides, there does not appear to be a concern at this time that would warrant further

investigation. The Agency will continue to monitor the incident information and if a concern is triggered, additional analysis will be included in the risk assessment.